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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,715	02/13/2002	Jack A. Maggiore	BMT-107	6774

7590 09/22/2005

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/074,715	Applicant(s) MAGGIORE ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *12-18,20-22 and 32*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 5. Applicant's reply has overcome the following rejection(s): 35 USC 112, first and second paragraph, rejections of claims 12-18, 20-22, and 32.

ADVISORY ACTION

Applicant's Response

1. Applicant's response, filed August 2, 2005 is acknowledged. Currently, claims 12-18, 20-22, and 32 are pending and are under examination.

Withdrawn Rejections

2. In light of Applicant's argument, the rejection of claims 12-18, 20-22, and 32 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

3. In light of Applicant's argument, the rejection of claims 12-18, 20-22, and 32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 12-18, 20-22 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Steaffens et al. (US Patent 6,579,688) in view of Figard (US Patent 5,616,460) for reasons of record.

Response to Arguments

5. Applicant's arguments filed August 2, 2005 have been fully considered but they are not persuasive.

A) Applicant argues that the combination of the teaching of Steaffens et al. with that of Figard et al. does not render obvious the claimed invention because the composition of claim 12 "consists essentially of" specified amounts of chelating agent, cell lysing agent, a preservative, and an antifreeze, in water, and is suitable for lysing and preserving a blood sample for hormone analysis. According to Applicant, the composition is capable of preserving thyroid stimulating hormone present in blood sample for at least about 3 weeks in ambient temperature of about 22C. Applicant specifically contends that by using the transitional phrase "consisting essentially of", claim 12 excludes other active ingredients.

In response, it is noted that claim 12 is read to *consist essentially of* chelating agent and cell lysing agent with specified concentration parameters and water. Parts c) and d) of claim 12 which recite "up to 0.1 weight percent of a preservative" and "up to 50 weight percent of antifreeze agent", respectively, read on "zero weight percent of a preservative" and "zero weight percent of antifreeze agent". Hence, the preservative and antifreeze having the required concentration parameters included therein, are not recited to be required in the claimed composition. Alternatively, Steaffens et al. disclose a stabilizing composition suitable for preserving biological fluid specimen having polypeptides and antigens. The composition consists essentially of ethylenediaminetetraacetic acid or EDTA as chelating agent and a cell lysing or dispersing agent (solubilizing agent such as ethanol) (see column 8, line 31 to column 9, line 14). The composition further may further consist of a preservative such as butylated hydroxy anisole or BHA, MICROCIDE II, gentamycin sulfate, and sodium azide and ethylene glycol (antifreeze agent) (see column 4, line 33 to column 5, line 6). Steaffens et al. teach adding EDTA concentrations of 0.05 to about 0.5 weight percent (0.01mM to 100mM), cell lysing agent concentration of 5 to about 25 percent (0.1% to 30% w/v), and a preservative concentration of 0.1 weight percent (0.01% to 10% w/v) (see column 6, lines 12-43).

In as far as the teaching of BSA or FCS (serum) as being included in the composition taught by Steaffens et al., it appears that BSA or FCS is used only as a "protein diluent" for the solution and does not appear to contribute to or materially affect the stabilizing or preserving capability of the composition. In column 8, lines 56-64,

Steaffens et al. specifically disclose that a cell lysing agent or dispersing agent (solubilizing agent and/or detergent) and chelating agent such as EDTA are added to enhance stability, i.e. to enhance preservation capacity. As sent forth in the MPEP, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials "and those that do not materially affect the basic and novel characteristics" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355.

B) Applicant argues that the combination of the teaching of Steaffens with that of Figard does not render obvious the claimed invention because there is no teaching, suggestion, or motivation to have combined the two references to arrive at the specific composition recited in the claims. Applicant specifically contends that Steaffens or

Figard does not teach or suggest a composition as set forth in the present claims that is capable of preserving TSH within a blood sample for 3 weeks at 22 C.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Steaffens et al. disclose a stabilizing composition which consists essentially of EDTA as chelating agent and cell lysing agent (ethanol or solubilizing agent). The composition also includes a preservative and antifreeze agent. Since Steaffens et al. does not teach a concentration parameter outside of zero weight percent, i.e. 1 up to about 50 weight percent of antifreeze agent, Figard was incorporated therein only for the disclosure of ethylene glycol (anti- freeze agent) used for its superior ability to preserve binding capacity of antibodies to antigens in biological fluids at concentrations of up to 50 weight percent (4% to about 8% weight per unit volume) in a composition. Accordingly, one of ordinary skill in the art at the time of the instant invention would have been motivated to use anti-freeze agent at concentrations taught by Figard in the preserving biological compositions taught by Steaffens because Figard found that ethylene glycol used in such concentrations provide superior preserving capacity in binding interactions between polypeptides. Additionally, it has long been settled to be no more than routine

experimentation for one of ordinary skill in the art to discover an optimum values or ranges of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955).

In response to applicant's argument that Steaffens or Figard does not teach or suggest a composition as set forth in the present claims that is capable of preserving TSH within a blood sample for 3 weeks at 22 C, the discovery of a new inherent property of a known stabilizing composition, discovered to characteristically preserve TSH in blood sample for 3 weeks at 22 C, does not render the product novel, unless otherwise, rendered novel or nonobvious from a modification or variation of its original structure that is structurally different, novel, and nonobvious. Further, a recitation of the intended use of the claimed product must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571)

272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
September 7, 2005

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09/16/05